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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,613	07/18/2002	Oystein Rekdal	1181-258	3472

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EXAMINER

DESAI, ANAND U

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 04/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/069,613	Applicant(s) REKDAL ET AL.	
	Examiner Anand U. Desai, Ph.D.	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6,8,9,11,13,18-20 and 24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6,8,9,11,13,18-20 and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. This office action is in response to Amendment filed on January 11, 2004. Claims 1-5, 7, 10, 12, 14-17, 21-23 have been previously cancelled. Claims 6, 8, 9, 11, 13, 18-20, and 24 are currently pending and are under examination.

Withdrawal of Rejections

2. The rejection of claims 6, 8, 9, 11, 13, 18-20, and 24 under 35 U.S.C. 112, 2nd paragraph is withdrawn based on Applicants amendment and remarks.

3. The rejection of claim 18 under 35 U.S.C. 112, 1st paragraph is withdrawn based on Applicants amendment.

Maintenance of Objections and Rejections

Specification

4. The disclosure is objected to because of the following informalities:

5. On page 16, line 23, the word, "my" appears to be intended to be "may."

Appropriate correction is required.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Art Unit: 1653

7. Claims 6, 8, 9, 11, 13, 18, 19, 20, and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Svendsen et al. US 2003/0022821 A1 (Effective filing date=August 28, 1998). Svendsen et al. disclose modified lactoferrin peptides and a method of synthesizing the peptides using solid phase synthesis, which are 7 to 25 amino acids in length, with three or more cationic residues and which is optionally capable of forming an amphiphatic α -helix. Svendsen et al. also disclose a lactoferrin peptide that can introduce, by addition or substitution, an extra bulky and lipophilic amino acid (e.g. tryptophan); One bioactive peptide is the lactoferrin bovine fragment amino acids 17-41 which is 25 amino acids, with 8 cationic amino acids (see US 2003/0022821 A1, paragraph 7, also Table/Figure 1, paragraph 222, example 3, paragraph 242, Table 3, paragraph 263, paragraph 92, claims 1-18, current application, claims 6, 8, 9, 11, 13, and 24). Svendsen et al. disclose the use of a modified lactoferrin peptide as a medicament (see US 2003/0022821 A1, claims 12, and 18, current application, claims 19, and 20) to treat tumors in patients (see US 2003/0022821 A1, paragraph 364, example 16, claims 14, and 18, current application, claim 18).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Art Unit: 1653

Response to Remarks

Applicants traverse the rejection of claims 6, 8, 9, 11, 13, 18-20, and 24 under 35 U.S.C. 102(e). Applicants state the claims of the present application are directed to a method of producing a peptide having certain characteristics. Applicants state the reference US 2003/0022821 A1 does not teach, disclose, or suggest the particular claimed method for producing a peptide having these features. Therefore the reference does not anticipate the presently claimed invention. This argument is not found persuasive.

Svendsen et al. does describe modified lactoferrin peptides and a method of synthesizing the peptides using solid phase synthesis, which are 7 to 25 amino acids in length, with three or more cationic residues and which is optionally capable of forming an amphipathic α -helix (see paragraph 88, and 94+). For one to be in possession of the peptide, the peptide must be synthesized. In paragraph 72, Svendsen also describes the state of the prior art, suggesting that it is now "commonplace" in the art to replace peptide or protein-based active agents e.g. therapeutic peptides with such peptidomimetics having functionally-equivalent activity. Various molecular libraries and combinatorial chemistry techniques exist and are available to facilitate the identification, selection, and/or synthesis of such compounds using standard techniques (citing Kieber-Emons, T. et al. Current Opinion in Biotechnology 1997 8: 435-441). Since it is "commonplace" to synthesis peptidomimetics it would equally be "commonplace" to synthesis the lactoferrin peptide. In addition, paragraphs 222, 242, and 244 do describe the solid phase synthesis of lactoferrin analogs.

Art Unit: 1653

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

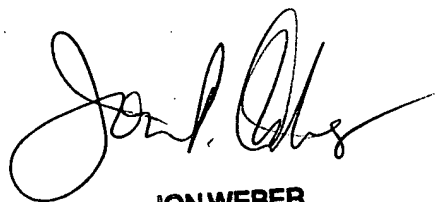
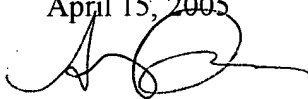
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U. Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 7:00 a.m. - 3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (517) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

April 15, 2005



JON WEBER
SUPERVISORY PATENT EXAMINER